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ACUTE ORAL TOXICITY UP AND DOWN PROCEDURE IN RATS

PROTOCOL NO.:	P203 UDP
STUDY NUMBER:	13265
SPONSOR:	REACT-NTI LLC 1 Whispering Spring Drive Freehold, NJ 07728
TEST SUBSTANCE IDENTIFICATION:	ALL-Natural Batch #2161
TEST SUBSTANCE DESCRIPTION:	White to pale yellow powder
DATE RECEIVED:	February 11, 2003
PSL REFERENCE NO.:	030211-5H
DATES OF TEST:	February 24 - March 11, 2003
NOTEBOOK NO.:	03-07: pages 66-66A, 67-73

1. PURPOSE

To provide information on health hazards likely to arise from a short-term exposure to ALL-Natural by the oral route.

2. PROCEDURE

A group of Sprague-Dawley derived, albino rats was received from Ace Animals, Inc., Boyertown, PA. The animals were singly housed in suspended stainless steel caging with mesh floors. Litter paper was placed beneath the cages and was changed at least three times per week. The animal room was temperature controlled and had a 12-hour light/dark cycle. The animals were fed Purina Rodent Chow #5012 and filtered tap water was supplied *ad libitum* by an automatic watering system.

Following acclimation to the laboratory, a group of animals was fasted overnight by removing the feed from their cages. After the fasting period, three female rats were selected for test based on health and initial body weights. Females were selected for the test because they are frequently more sensitive to the toxicity of test compounds than males. Individual doses were calculated based on the initial body weights, taking into account the specific gravity (determined by PSL) and the concentration of the test substance. Each animal received an appropriate amount of the test substance, administered as an 18% w/w suspension in 1% w/w carboxymethylcellulose (CMC) in distilled water, by oral intubation using a stainless steel ball-tipped gavage needle attached to an appropriate syringe. Preliminary solubility

testing conducted by PSL determined concentrations in excess of 18% (i.e., 20%-50%) were too viscous to be administered properly. Due to the high volume of test suspension to be administered, each animal's dose was divided into two equal portions, administered 2 hours apart. After administration, each animal was returned to its designated cage. Feed was replaced approximately 3-3.5 hours after dosing.

An initial limit dose of five thousand milligrams of the test substance per kilogram of body weight was administered to one healthy female rat by oral gavage. Due to the absence of mortality in this animal, two additional females received the same dose level. Since all three animals survived, no additional animals were tested. The animals were observed for mortality, signs of gross toxicity and behavioral changes for several hours post-dosing and at least once daily for 14 days. Body weights were recorded prior to test substance administration (initial) and again on Days 7 and 14 (termination). All rats were euthanized by CO_2 inhalation at study termination. Necropsies were performed on all animals.

Individual animals were dosed as follows:

Dosing Sequence	Animal No.	Sex Dosed	Dose Level (mg/kg)	Short-term Outcome	14-Day Outcome
1	7807	F	5,000	S	S
2	7848			S	S
3	7849			S	S

S – Survival

3. RESULTS

Individual body weights and doses are presented in Table 1. Individual cage-side and necropsy observations are presented in Tables 2 and 3, respectively.

All animals survived exposure to the test substance. Following test substance administration, the single clinical observation noted was soft feces for one animal which cleared by Day 2 and all animals appeared active and healthy, gaining body weight over the entire 14-Day observation period. Gross necropsy findings at terminal sacrifice were unremarkable.

4. CONCLUSION

Under the conditions of this study, the acute oral LD_{50} of ALL-Natural is greater than 5,000 milligrams of the test substance per kilogram of body weight in female rats.

SIGNATURES

ALL-Natural

We, the undersigned, declare that the methods, results and data contained in this report faithfully reflect the procedures used and raw data collected during the study.

George E. Moore, B.S.
Study Director

05/07/03
Date

Rhonda S. Krick, B.S.
Quality Assurance Director

05/07/03
Date

TABLE 1: INDIVIDUAL BODY WEIGHTS AND DOSES

Animal No.	Sex	Dose Level (mg/kg)	Body Weight (g)			Dose[1]
			Initial	Day 7	Day 14	ml
7807	F	5,000	192	219	236	5.0
7848	F	5,000	200	218	236	5.2
7849	F	5,000	190	216	233	5.0

[1] Administered as an 18% w/w suspension in 1% w/w carboxymethylcellulose (CMC) in distilled water. Specific Gravity – 1.062 g/ml.

TABLE 2: INDIVIDUAL CAGE-SIDE OBSERVATIONS

Animal Number	Findings	Day of Occurrence
FEMALES		
7807, 7848	Active and healthy	0-14
7849	Active and healthy Soft feces	0(0.5-5 hr), 2-14 1(PM)

TABLE 3: INDIVIDUAL NECROPSY OBSERVATIONS

Animal Number	Tissue	Findings
FEMALES		
7807, 7848, 7849	All tissues/organs	No gross abnormalities